Subject: Corrective Action SOP Update (austin 2/17)

Location: room 202

Start: 2/26/2010 9:30 AM

End: 2/26/2010 10:30 AM

Show Time As: Busy

Recurrence: (none)

Meeting Status: Accepted

Organizer: Nagle, Austin (DPH)

Required Attendees: Clemmer, Jill (DPH); Han, Linda (DPH); Chen, Karen (DPH); Jenner, Jennifer (DPH); DiNatale, Margaret (DPH)

Resources: room 202

When: Friday, February 26, 2010 9:30 AM-10:30 AM (GMT-05:00) Eastern Time (US & Canada).
Where: room 202

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<<corr action form part 1.doc>> <<corr action form part 2.doc>> <<QA.009 corr action old format .doc>>

I am convening a small working group to update the QA SOP .009 Corrective Action and the forms that accompany the procedure. During out last CLIA Inspection Charlie recommended that we use our formal corrective action procedure for sentinel events that impact patient care. This includes incorrect results, incorrect result interpretations and proficiency test failures. For CLIA compliance the corrective action process for such events needs to include the following components:
1. Formal root cause analysis (investigation) to identify problem and causes
2. Identified cause and corrective actions implemented
3. Short term and long term corrective action plan
4. Follow-up and outcomes
Our existing forms, which I attached, meet these requirements but can be updated to make this a smoother process for both the Lab and QA. Things to consider as part of the updating process:
· Should the timeline be changed to complete parts 1 and 2?
· Should we continue using two forms or merge it into one? If one form is used, what is the timeline for follow-up and outcomes? How should this be tracked?
· If one form is used, which sections should be retained or renamed?
· Should the existing review process be changed?
I look forward to working with you and enhancing our existing corrective action process.
Thanks…..Dina